

## SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General of the Department of Health and Human Services (“HHS-OIG”) (collectively, the “United States”), Defendant BSN Medical Inc., and Relator Bruce Carroll (hereafter collectively referred to as “the Parties”), through their authorized representatives.

### RECITALS

A. BSN Medical Inc. is a medical device and equipment manufacturer located in Charlotte, North Carolina, that specializes in the areas of compression therapy, wound care and orthopedics.

B. On August 14, 2017, Relator Bruce Carroll filed a *qui tam* action in the United States District Court for the Western District of North Carolina captioned *United States ex rel. Bruce Carroll, Bringing this Action on Behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, Virginia, and Washington, The District of Columbia, and the cities of Chicago, New York and Philadelphia, and the County of Allegheny, Pennsylvania v. BSN Medical Inc., and John Does, 1 through 100*, Case No. 317-cv-480, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). Relator alleged that Defendants knowingly, (1) paid remuneration to induce purchases of its Total Contact Casting kits in violation of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and (2) fraudulently advertised and promoted various products in connection with certain healthcare common procedure coding system (“HCPCS”) codes, without first obtaining verification for the products through the appropriate Pricing Data

and Analysis Coding contractor (the “PDAC”), or, for which the PDAC verification had expired, to customers; which caused the submission of false claims to the Medicare and Medicaid programs.

C. The United States contends that BSN Medical Inc. caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395III (“Medicare”) and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 (“Medicaid”).

D. The United States contends that it has certain civil claims against BSN Medical Inc. arising from its marketing and promotion of various products that did not meet Medicare and Medicaid’s reasonable and necessary requirements as BSN Medical Inc. had either not obtained PDAC approval or for which PDAC approval had expired, in connection with HCPCS Codes E2607, L0625 and L0626, during the timeframe January 1, 2015 through December 31, 2017. The products at issue are identified by BSN product number, and are limited to those contained in the following table:

13-121PK	70-910642	70-160344
13-123PK	70-910749	70160441
13-124PK	70-910846	70-160548
13-127PK	70-120443	70-160645
13-701PK	70-120540	70-160742
13-702PK	70-120647	70-160849
70-910341	70-120744	70160946
70-910448	70-120841	73-130
70-910545	70-122946	34-6304
34-6306	31-208UNSTD	31-208SMSTD
31-208MDSTD	31-208LGSTD	31-2081LSTD
31-2082LSTD	91-2083LSTD	31-2084LSTD
31-103401	31-103503	31-103605
31-103702		

That conduct is referred to below as the “Covered Conduct.”

E. This Settlement Agreement is neither an admission of liability by BSN Medical Inc., nor a concession by the United States that its claims are not well founded. BSN Medical Inc.

denies the United States' allegations in Paragraph D and the Relator's allegations set forth in the Civil Action.

F. Relator claims entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relator's reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

#### TERMS AND CONDITIONS

1. BSN Medical Inc. shall pay to the United States and the Medicaid Participating States SEVEN HUNDRED EIGHTY- FIVE THOUSAND SIX HUNDRED SEVENTY-TWO DOLLARS and FOURTEEN CENTS (\$785,672.14), the "Settlement Amount", and interest on the Settlement Amount at a rate of 1.5% per annum from the Effective Date of this Agreement, of which THREE HUNDRED NINETY-TWO THOUSAND EIGHT HUNDRED THIRTY-SIX DOLLARS and SEVEN CENTS (\$392,836.07) is restitution, no later than thirty (30) days after the Effective Date of this Agreement. From the Settlement Amount, BSN Medical Inc. shall pay to the United States FIVE HUNDRED FIFTY THOUSAND FIVE HUNDRED TWENTY-SIX DOLLARS and SIXTY-FOUR CENTS (\$550,526.64) by electronic funds transfer pursuant to written instructions to be provided by the Office of the United States Attorney for the Western District of North Carolina. From the Settlement Amount, BSN Medical Inc. shall pay to the Medicaid Participating States TWO HUNDRED THIRTY-FIVE THOUSAND ONE HUNDRED FORTY-FIVE DOLLARS and FIFTY CENTS (\$235,145.50) in full and final settlement of the Medicaid Participating States' claims against BSN for the Covered Conduct. This amount will be paid to the States by instructions to be provided by the States' counsel.

2. Subject to the exceptions in Paragraph 4 (concerning reserved claims) below, and conditioned upon receipt of the full Settlement Amount, the United States releases BSN Medical Inc. together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, and the corporate successors and assigns of any of them, from any civil or administrative monetary claim the United States may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. Subject to the exceptions in Paragraph 4 below, and conditioned upon full payment of the Settlement Amount, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases BSN Medical Inc. together with its current and former parent corporations, direct and indirect subsidiaries, brother or sister corporations, divisions, and the corporate successors and assigns of any of them from any civil monetary claim the Relator has on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733 and N.C.G.S. § 1-605, *et seq.*

4. Notwithstanding the releases given in Paragraphs 2 and 3 of this Agreement, or any other term of this Agreement, the following claims and rights of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability or enforcement right, including mandatory or permissive exclusion from Federal health care programs;

- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement; and
- f. Any liability of individuals.

5. Relator and his heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon the United States receiving the Settlement Amount and as soon as feasible after receipt, the United States shall pay \$110,105.33 to Relator by electronic funds transfer (Relator's Share).

6. BSN Medical Inc. agrees that it is liable for the payment of THREE HUNDRED AND THREE THOUSAND SIX-HUNDRED AND THREE DOLLARS AND NINETY-THREE CENTS (\$303,603.93) to Relator pursuant to 31 U.S.C. § 3730(d)(1) for expenses or attorneys' fees and costs. This single payment is due on or before August 19, 2022, by electronic funds (wire) transfer pursuant to written instructions to be provided by Relator as soon as practicable. Upon receipt of full payment, Relator, for himself and for his heirs, successors, attorneys, agents, and assigns, releases BSN Medical Inc., and its officers, agents, and employees, from any further and additional liability to Relator arising from the filing of the Civil Action, or under 31 U.S.C. § 3730(d) for expenses or attorneys' fees and costs.

7. BSN Medical Inc. waives and shall not assert any defenses BSN Medical Inc. may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

8. BSN Medical Inc. fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that BSN Medical Inc. has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct or the United States' investigation or prosecution thereof.

9. BSN Medical Inc. fully and finally releases the Relator from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that BSN Medical Inc. has asserted, could have asserted, or may assert in the future against the Relator, related to the *qui tam* complaint and the Relator's investigation and prosecution thereof.

10. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare and/or Medicaid contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier, or any state payer or state contractor), related to the Covered Conduct; and BSN Medical Inc. agrees not to resubmit to any Medicare/Medicaid contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

11. BSN Medical Inc. agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395III and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of BSN Medical Inc., its present or former officers, directors, employees, shareholders, and agents in connection with:

(1) the matters covered by this Agreement;

- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) BSN Medical Inc.'s investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment BSN Medical Inc. makes to the United States pursuant to this Agreement and any payments that BSN Medical Inc. may make to Relator, including costs and attorneys' fees.

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by BSN Medical Inc., and BSN Medical Inc. shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by BSN Medical Inc. or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: BSN Medical Inc. further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program,

including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by BSN Medical Inc. or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. BSN Medical Inc. agrees that the United States, at a minimum, shall be entitled to recoup from BSN Medical Inc. any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by BSN Medical Inc. or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on BSN Medical Inc. or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine BSN Medical Inc.'s books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 13 (waiver for beneficiaries paragraph), below.

13. BSN Medical Inc. agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.



14. Upon receipt of the payment described in Paragraph 1, above, the Relator and United States shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1). Such dismissal shall be (1) with prejudice to the Relator with respect to all claims against BSN Medical Inc. under 31 U.S.C. § 3729-33; (2) with prejudice to the United States with respect to the Covered Conduct; and (3) without prejudice to the United States with respect to all other claims.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

16. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

17. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Western District of North Carolina. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

18. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

19. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

20. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

21. This Agreement is binding on BSN Medical Inc.'s successors, transferees, heirs, and assigns.

22. This Agreement is binding on Relator's successors, transferees, heirs, and assigns.

23. All Parties consent to each Party's disclosure of this Agreement, and information about this Agreement, to the public.

24. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

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**THE UNITED STATES OF AMERICA**

DATED: 08/05/2022

BY: KATHERINE ARMSTRONG  
DENA J. KING  
UNITED STATES ATTORNEY

Digitally signed by KATHERINE  
ARMSTRONG  
Date: 2022.08.05 14:56:15 -04'00'

KATHERINE T. ARMSTRONG  
Assistant United States Attorney  
Western District of North Carolina

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**BSN MEDICAL INC. - DEFENDANT**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Kevin Gorman  
Vice President, Legal & General Counsel

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Zane David Memeger  
Morgan, Lewis & Bockius LLP  
Counsel for BSN Medical Inc.

**BRUCE CARROLL - RELATOR**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BRUCE CARROLL  
Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Charles H. Rabon, Jr.  
Rabon Law Firm, PLLC  
Counsel for Relator Bruce Carroll

**THE UNITED STATES OF AMERICA**

DATED: 08/05/2022

BY: \_\_\_\_\_

DENA J. KING  
UNITED STATES ATTORNEY

KATHERINE T. ARMSTRONG  
Assistant United States Attorney  
Western District of North Carolina

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

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BY: \_\_\_\_\_

Kevin Gorman  
Vice President, Legal & General Counsel

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Zane David Memeger  
Morgan, Lewis & Bockius LLP  
Counsel for BSN Medical Inc.

**BRUCE CARROLL - RELATOR**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

BRUCE CARROLL  
Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Charles H. Rabon, Jr.  
Rabon Law Firm, PLLC  
Counsel for Relator Bruce Carroll

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
DENA J. KING  
UNITED STATES ATTORNEY

KATHERINE T. ARMSTRONG  
Assistant United States Attorney  
Western District of North Carolina

DATED: 8/12/2022

BY: Lisa M. Re / RmP  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**BSN MEDICAL INC. - DEFENDANT**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Kevin Gorman  
Vice President, Legal & General Counsel

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Zane David Memeger  
Morgan, Lewis & Bockius LLP  
Counsel for BSN Medical Inc.

**BRUCE CARROLL - RELATOR**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BRUCE CARROLL  
Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Charles H. Rabon, Jr.  
Rabon Law Firm, PLLC  
Counsel for Relator Bruce Carroll

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
DENA J. KING  
UNITED STATES ATTORNEY

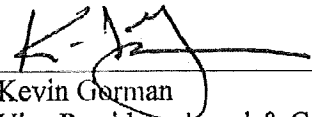
KATHERINE T. ARMSTRONG  
Assistant United States Attorney  
Western District of North Carolina

DATED: \_\_\_\_\_

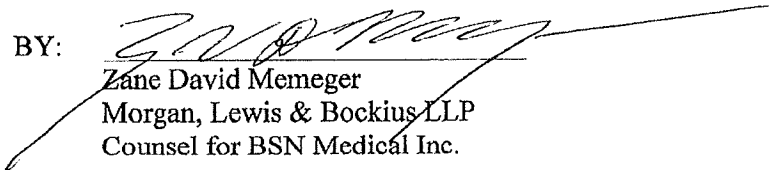
BY: \_\_\_\_\_  
LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**BSN MEDICAL INC. - DEFENDANT**

DATED: 8/5/22

BY:   
Kevin Gorman  
Vice President, Legal & General Counsel

DATED: 8/5/22

BY:   
Zane David Memeger  
Morgan, Lewis & Bockius LLP  
Counsel for BSN Medical Inc.

**BRUCE CARROLL - RELATOR**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
BRUCE CARROLL  
Relator

DATED: \_\_\_\_\_

BY: \_\_\_\_\_  
Charles H. Rabon, Jr.  
Rabon Frazier LLP  
Counsel for Relator Bruce Carroll

**THE UNITED STATES OF AMERICA**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

DENA J. KING  
UNITED STATES ATTORNEY

KATHERINE T. ARMSTRONG  
Assistant United States Attorney  
Western District of North Carolina

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

LISA M. RE  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
United States Department of Health and Human Services

**BSN MEDICAL INC. - DEFENDANT**

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Kevin Gorman  
Vice President, Legal & General Counsel

DATED: \_\_\_\_\_

BY: \_\_\_\_\_

Zane David Memeger  
Morgan, Lewis & Bockius LLP  
Counsel for BSN Medical Inc.

**BRUCE CARROLL - RELATOR**

DATED: 8/8/2022

BY: Bruce M. Carroll Jr.

BRUCE CARROLL  
Relator

DATED: 8/9/2022

BY: Charles H. Rabon, Jr.

Charles H. Rabon, Jr.  
Rabon Law Firm, PLLC  
Counsel for Relator Bruce Carroll